User

Operating Instructions

WD230, WD250, WD290

CE 0044

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Belimed
Infection Control

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1. Used symbols

Danger!

Situation or facts that immediately to a negative impact may result. From this impact can persons, things, situations and environment.

⚠ ! IMPORTANT NOTES ! ⚠

Please, carefully study these notes prior to starting the machine.

Limits of Liability

The manufacturer assumes no responsibility for losses resulting from operational errors, other than intended application, resulting from operation by operators not specifically trained in the operation of the machine or failure to follow instructions provided by the operations manual. Unless authorized in writing by the manufacturer, any changes, especially design changes, made by unauthorized personnel result in the total waiver of warranty as well as the loss of product liability.

The cleaning automat may be used only for applications as described and for reusable medical products in the operations manual.

This machine is designed for exclusive application inside of rooms and in the hospital environment. Application for cleaning of textile products may lead to damage to the machine. Operation of the machine is permitted by specifically trained personnel only.

! CAUTION !

Cleaning Performance

Proper performance is possible only under provisions of:

- **Validation of program parameters such as dosing and appropriate assignment of media at time of start-up by qualified personnel,**
- **Free and unencumbered rotation or wash arms,**
- **Proper loading of load carriers under observation of operating instructions,**
- **Proper alignment of docking features of load carrier and machine,**
- **Use of original load carriers intended for operation with this machine (no foreign products),**
- **Presence of all course sieves and wash arms, all properly and regularly cleaned,**
- **Proper and timely executed preventive maintenance procedures by technical personnel.**

Especially the clean filters and the dosing pumps must be regularly serviced and checked.

Validation

The pre-eminent goal of process validation in the spirit of the medical product laws is achievement of a high degree of safety in the realm of reconditioning of medical products. This in the sense of protection of patients and protection of the reconditioning personnel. The initial validation always consists of the elements The initial acceptance, function and performance assessment.

! WARNING !

The user is responsible for checking the general cleanliness of the machine and proper performance of the machine following each use.

Safe sterilization is possible only with clean medical products, i.e. properly maintained and cleaned machines. It is mandatory to check proper performance of the machine. Judged under condition of normal or to normal corrected eyesight, no remnants of dirt (crusts, coatings) must be found on any part following cleaning / disinfecting the machine.

The entire disinfecting program may not be interrupted for any reason at any time whatsoever. Following each interruption, the program must be reset and repeated by means of the "I/O" switch.

Should it become necessary to interrupt the disinfecting process on account of some imminent danger, the wash chamber door must not be opened for about five minutes. This is to allow health risk vapors to dissipate.

Following the drying process, metallic wash goods are very hot and may lead to burn injuries if wash goods are removed without the use of gloves.

During the act of replenishing cleaning and disinfecting agents, it is mandatory to wear protective gear for eyes, hands and clothing. Proper handling of all additives, it is necessary to wear gloves. Do not ingest additives and prevent eye and skin contact!

Make certain that the proper additives are filled or replaced in containers.

! DANGER !

Under following conditions, the machine must be shut off immediately:

- **Appearance of smoke,**
- **Water escapes from machine,**
- **Glass door is cracked or otherwise defective.**

Advise tech service immediately.

Cut power before conducting any repairs or service of machine.

Door Function

Closing of automatic door may not be done manually or by activating safety door switch but only by button "I – O". In case any objects are jammed between outer machine body and door, technical personnel must be informed.

If a program got interrupted with the I/O button, during a program cycle, the UC and CS doors stays interlocked. On the display instead of "Program ready" "Door Interlock" is shown. The Door can be opened only if a program is run successfully till to the end

Machine Enclosure

The machine may be operated only with the entire enclosure in place. A pipe rupture could otherwise lead to severe burns by hot water. Be reminded that the operating water temperature is 93°C.

2. Requirements for hygienic reconditioning

2.1 instruction of personnel

The device may only be used by authorized, trained personnel operated, maintained and repaired. This assumes that the present instructions read and understood.
Responsibilities and competences in operation, maintenance and repair must be clearly defined and adhered to. For the operation and maintenance staff is competent regularly to schools on how to deal with the equipment and detergents. It is recommended a training proof.

The operator is always solely responsible for the hygienic safety of the reconditioned medical goods (cleaning merchandise). The operator of the decontamination and disinfection unit WD usually is found in the owner of the WD. The manufacturer of the WD is always responsible for the safety related quality of the WD. This for as long as the user has operated the WD under careful observance of instructions pertaining to operation, maintenance and service. Comprehensive maintenance of the WD includes servicing, inspections, repairs and the hygienic reconditioning. The operator may only task personnel that is in possession of the required professional knowledge, all prerequisites and the required means.

The hygienic reconditioning of a medical product (wash goods) is acceptable only if processed according to the state of the art and technology; of special importance is that the user is proceeding under exact pursuit of the guidelines issued by the manufacturer of the medical product.

Preceding the actual reconditioning activities, the feasibility of reconditioning, the development and the application of validated procedures for the individual reconditioning steps, the material properties and the function of the medical product must be checked.

It is, therefore, recommended to define and set up rules of responsibilities and standard operating procedures (SOP) for the loading and for the related programs. This is to warrant the highest level of confidence for repetitive execution of the respective processing steps. The reference loading depends on the risk group and must be validated by respective cleanliness tests.

When setting up standard operating procedures (SOPs), the following critical factors must be investigated and defined by rules:

- Which categories of instruments can not or only marginally decontaminated by mechanized means on account of their shape (hallow bodies, lumen, bottlenecks in channels, check flaps)?
- Is the intended reconditioning process appropriate when checked against the material properties of the cleaning goods and has the material compatibility with respect to chemicals and process temperatures been properly considered?
- Have risk levels been established for the pre-cleaning of the wash goods according to established risk groups (RKI provisions)?
- Have transport channels and disposal dwell time (baking on and degree of contamination) been considered?
- Are the various degrees of contamination by ointments, bone meal, dried blood been considered during pre-cleaning and in the realm of program selection?
- Are all operating instructions, reconditioning provisions for medical products being heeded?
- Is there a maintenance plan available and are inspections carried out?

The responsibility for proper execution of hygienic reconditioning is always squarely attributed to the operator.

3. Application areas of the WD

- Surgical instruments
- Minimally invasive instruments
- Instruments for anesthetics and intensive care
- Baby bottles and suckers
- Containers
- OP shoes
- Laboratory gadgets for research and production

Instruments reconditioning is preferably executed by means of thermal disinfection.

4. General directives for processing of medical products

4.1 Preparation of medical products prior to processing

Basically all outer and inner surfaces must be physically accessible for the selected decontamination, disinfecting and sterilization means (open all valves / faucets and hinged tools!). Special attention is required for lumens. More complex medical products may need to be dismantled. MIC instruments must be knocked down according to manufacturer's instructions. Baked on contamination residues are of heightened concern for invasive operating instruments. This is due to the fact that narrow openings are often difficult to remove with mechanized decontamination processing. Manufacturer's directives must be heeded (DIN EN ISO 17664 describe information that must be obtained from manufacturers pertaining to reconditioning of sterile medical products).

!IMPORTANT NOTES!

Not all medical products are suited for mechanized processing. It is for this reason that they must be sorted at the time of acceptance and certain items processed in a separate pre-cleaning (ultra-sonic) process.

Heavily soiled medical products should be pre-cleaned immediately following their application. Drying of blood and tissue on instruments must be precluded through proper procedures such as wiping off and flushing of operating channels and ducts immediately following instrument application. This has an immediate beneficial effect in decontamination effectiveness of the automated cleaning process (e.g. through prevention of infectious viruses drying in protective colloids).

Ways and means of pre-cleaning are to be design in accordance with the subsequent preparation. Special attention is warranted in prevention of fusing of blood and proteins, foaming in RDG.

Obstruction of decontamination may be caused by:

- pre-treatment using aldehyde disinfectants
- pre-treatment using alcoholic solutions
- draining of antiseptic solutions over the wash goods
- aldehyde and alcohol vapors
- heat pre-treatment

!All these methods can cause fusing of proteins and may be responsible e.g. for conservation of prione infectiousness!

See recommendation of RKI (Robert Koch Institute in Germany see www.RKI.de)„ Hygiene requirements in preparation of medical products. Federal health newsletter 44 (2001) : 1115-1126

!IMPORTANT NOTES!

In case of manual cleaning in a dip or an ultra-sonic bath, small amounts of foam are permissible, even though problems may arise with bubble formation in narrow channels and with hollow bodies. When pre-cleaning with foaming tensides, followed by mechanized cleaning with the WD, even traces of foam tensides are causing significant interference.

The air bubbles contained in the foam establish a foam pad that may interfere with the decontamination and disinfection process, because air is an insulator and has thus a reduced capacity to transport heat energy as compared to water. Thus, foam represents a significant hygienic risk!

4.2 Directives for appropriate decontamination

4.2.1 Influence of time and temperature

The following topics must be taken into account when taking decisions on program selection and program parameters:

Chemicals and mechanical treatment must be given the necessary **time** to develop their effect. Never attempt to save on time for decontamination.

Immediate application of high temperature levels have a tendency of fusing proteins. It is for that reason that automated decontamination should always start with a generous cold pre-rinse. Cold pre-rinsing should be given ample time in order to prevent denaturizing of proteins . Absence of proteins is a prerequisite for absence of prions .

Alkaline decontamination is characterized by high effectiveness in dissolving protein and fatty residues. On the other hand it may lead to material modifications. Under this aspect it appears advisable to procure such medical products that are designed for alkaline decontamination.

As a rule of thumb in alkaline decontamination, increasing the temperature by 10°C equals doubling of the cleaning efficiency. I.e. alkaline cleaners can develop their rapid protein splitting hydrolytic capacity only in conjunction with elevated temperature. In case high temperatures cannot be employed for reasons of material protection, increasing the decontamination time allotment may be a compensating factor.

See Belimed factory programs.

4.2.2 Influence of water quality

The water quality has a significant influence of the cleaning effectiveness. The fresh water quality (CW and WW) must at least meet criteria for potable water . Problems with insufficient water quality are as follows:

- Calcium deposits
- Corrosion
- Plaque formation and de-coloration
- Water stains
- Reduced cleaning efficiency

The water quality characteristics for the various steps in water preparation such as CW, WW and DI water must be clearly defined and kept under surveillance. In the selection and dosing of additives, the available fresh water quality must be taken into account.

In addition to the chemical parameters of water, the respective micro biological quality must also be monitored .

Under consideration of the special nosocomial risks, periodical micro biological water analysis with respect to opportunistic and infectious spores is of great importance.

4.2.3 Correct and cleaning conform loading

Flexible endoscopes cannot be decontaminated with this WD.

Influence of load on cleaning performance

Proper loading of wash goods on rack does have an important influence on cleaning performance. It is for this reason that the following points must be given full attention:

- Instruments with hollow spaces, shafts, hoses, respiratory tract instruments must also be cleaned completely on their **inside**. For this purpose, specially adapted inserts such as the AN rack with rinsing feature must be applied.
- **Tipping over of containers**, such as container lids or light weight bowls must be prevented. Otherwise, large amounts of water may remain, thus enhancing the chances for lye contamination and dispersion. Also, the drying process is thus slowed.

Instrument rack

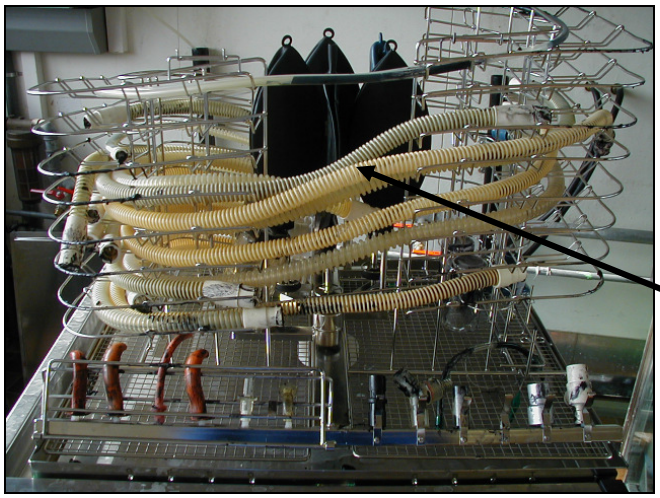
- Prerequisite for efficient automated decontamination is the appropriate loading of the wash goods racks.
- Articulated instruments must be loaded in open position
- Rack trays must not be overloaded
- Rotary spray arms must turn freely at all times
- Large surface instruments must be loaded such as not to cast a spray 'shade' for other instruments
- Motor components may be cleaned by automats only if expressly permitted by the manufacturer in conjunction with special procedures and mechanisms. Simple tools and accessory components may be processed similar to surgical instruments.

Container rack

Container lid: Watch for spraying shadows, the shallow side of lids and covers must point down

AN rack

Improperly loaded anesthetic hoses (incorrectly stuck on) may turn themselves loose from fixation, thus obstructing free rotation of wash arm. Such loosened ventilation hose may be insufficiently flushed and is thus not cleaned properly.



If **water remains in pockets** of hoses, such water is prevented from draining, delaying or preventing the drying process.

MIC rack

- MIC instruments and rigid endoscopes must be dismantled according to manufacturer specifications . This includes removal of seals and opening of valves . All hollow spaces must be able to be flushed. It is mandatory to use the Luer lock connectors found on the instrument racks and on the MIC rack that are designed for this purpose.

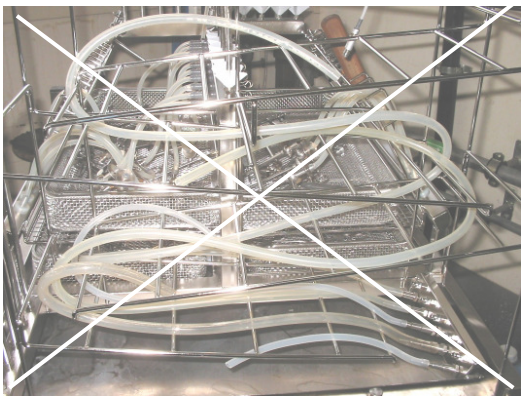
All hollow bodies must be flushed. For this purpose, use Luer Lock Connection set of instrument and/or MIC rack.

Funnel jets

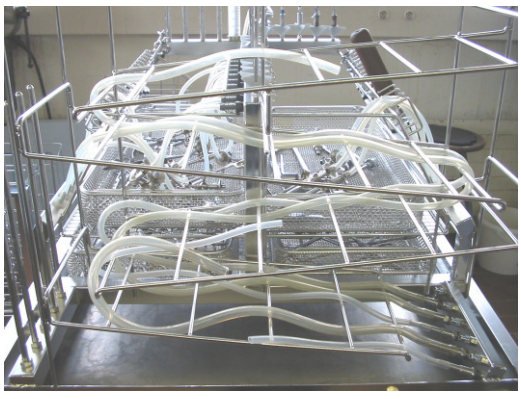
MIC instruments within the funnel jets are predominantly cleaned in the hollow chambers. Outer surface cleaning within the funnel jets is not quite as good, this is due to the fact that the flow velocity in those areas is reduced.

- Within the rack, silicon hoses must be properly fastened. That is to say that the hoses must not come loose from their brackets as a result of water pressure. Loose hoses may obstruct normal rotation of wash arms, thus hampering full surface cleaning action.

Improper loading



Correct loading



Influence of loading on dryer performance

Critical areas are for example: crimps on containers, OP shoe heels, water pockets in hoses, flipped over bowls, dead end hollow chambers of instruments. All of the above may prevent proper drainage of water, requiring evaporation.

If at all possible, wash goods should be self-draining. Required additional heating energy and related prolonged drying cycles for complete drying may be relatively high, thus accelerating the aging process of respective machinery components.

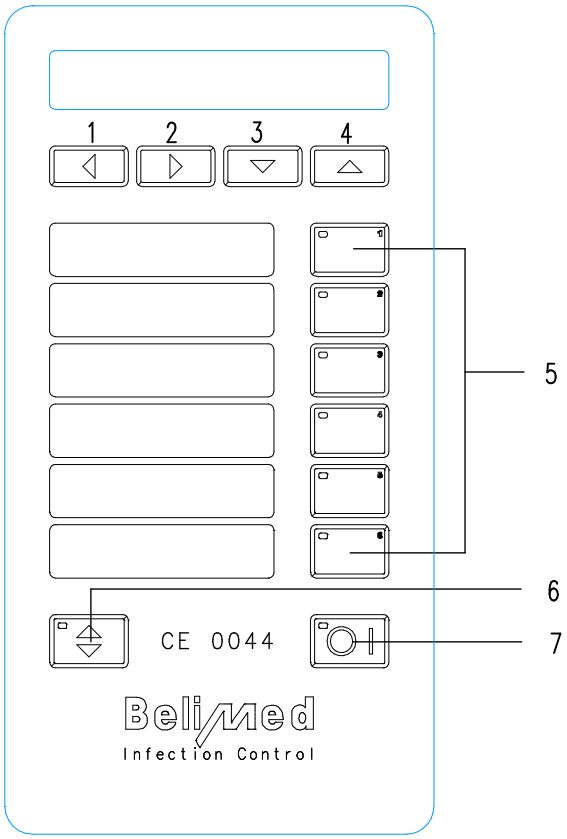
During offloading of wash goods, trapped water is drained, metallic wash goods subsequently dry within mere minutes.

In case of uncertainties, pleas contact your Belimed medical product consultant.

5. Operation, Keyboard

5.1 Keys unclean Side

Pic. 73091



Legend

1- 4 Arrow keys

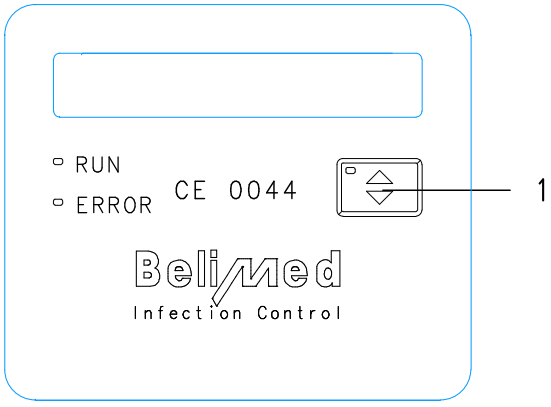
1. **Print operational data** such as program recipe and setup data.
   Activate **self-disinfection** ON / OFF
2. **Beeper** ON / OFF, at program end or in case of error acoustic signal occurs.
3. **Printer** ON / OFF
4. **Shift** key programs P7 - 12

Program keys (PT) 1, 2, 3, 4, 5, 6

5. **Selecting programs** P 1-6, with shift P 7-12
6. **Door button**, door open / close.
   With CS door open, beeper is activated with door button
7. **Reset and ON / OFF** (IO) button respectively.
   By pressing for 4 seconds, then releasing, batch number and machine No. is shown.

5.2 Keys clean Side

Pic. 73091



Legend

1 Door button (door open / close)

RUN = Operating

ERROR = Error

6. Operational Display

6.1 Normal Operation

Close the door by means of door button until the following display indication appears:

Program ready
Date Time

Check for proper date and time. The data are passed on to the batch documentation. The machine is now operational and may be started by program buttons P1 to P6.

6.2 Program Start

The machine may be started by program buttons P1 to P6 or by means of automatic program recognition found on lading rack. In case of automatic program recognition, any program may be overwritten manually (by program buttons) as long as door is open.

The program is launched only once the door is fully closed.

First, the program name, then status is shown on the display as follows:

P2 ◄■■ _ _ ► 13 Min
Cleaning 36 °C

P2	Program No. (P1 – P6, P7 – P12)
◄■ _ _ ►	Program step status, e.g. at program start S1
◄■■ _ _ ►	Status display at S2, with a total of 4 steps.
	End marking "◄ _ _ ►" represents the number of steps in the respective program.
13 Min	**Remaining run time** or remaining program time. Actual value plus saved last value / 2. At interrupt, value will be ignored.
Cleaning	Actual step phase
36 °C	Temperature of wash liquid or dryer air at intake of wash chamber.

6.3 Self-disinfection and complete drainage of DI tank

Explanation

To minimize the germ count as well as the endotoxine load on the medical product after the mechanized decontamination and disinfection processes to a minimum, a separate disinfection cycle must be applied. See also EN ISO 15883-1 chapter 5.3.1.1:

During a prolonged stand-still period, microorganisms form in the wash chamber, in the pipe ducts and in the DI tank. Even following a thermal disinfection step, remnants of the dead germs of the DI tank may represent a risk for patients (pyrogen-related reaction). Therefore, following each (inactive) weekend, the DI tank should be completely drained and the entire equipment thermally disinfected without any wash goods payload.

In case of active self-disinfection, the user or operator will be alerted to initiate a self-disinfection cycle at the end of a predetermined period of time.

It is recommended to carry out a self-disinfection following any 24 h or higher stand-still period.

!IMPORTANT NOTE!

The program self-disinfection must always be performed with an empty wash goods carrier.

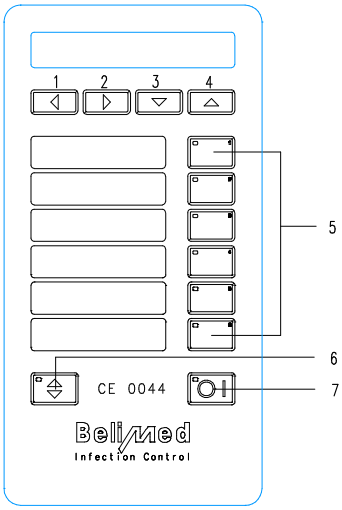
Never insert blood-clad or thermally instable wash goods!!

The automatic rack recognition is ignored.

Upon completion of a self-disinfection cycle, the clean side is not unlocked.

With the main switch in OFF position (supply interruption), timer is inactive. This is why at the time of turning power ON, the reminder is flashed on the display.

Activating function self-disinfection



Upon pressing left cursor button „◀“ (1) twice, display shows following:

Self-disinfection	
24 h	**ON/OFF**

By acknowledging the right cursor button „▲“(4), the automatic system disinfection is activated (ON) or de-activated (OFF).

Default is ON

In case of automatic self-disinfection and upon timer run-out (Setup settings chapter 5.1), program self-disinfection and and draining DI tank is queried or suggested on the display.

At setting 0 h, self-disinfection cannot be activated.

Instead of 'program ready', display shows:

Self-disinfection
Start

Launching self-disinfection

- Open door, **empty** wash goods rack. At a setting of 0 h, self-disinfection cannot be activated. **!CAUTION**! **Do not put any wash goods in machine!!!**
- The process may be launched by pressing any program button P1 to P6 (except I/O (7) and door button (6)) and only with door closed.

The display now shows

SD I I	**13 Min**
Disinf Ao 68	**89 °C**

If available, the DI tank is being drained. In case there is no DI tank, DI water will be used to fill the tank and then heated to 93 °C. The wash chamber will be thermally disinfected according to definition Ao = 3000.

!CAUTION!

Since the thermal disinfection is performed in the first water step without prior cold rinsing, no wash goods may be inserted!!

During the drain pump cycle, the DI tank is being **completely** emptied.

The chamber is subsequently dried briefly.

The program self-disinfection is of rigid nature and cannot be altered (Progr. 13).

Program self-disinfection SD

Thermal disinfection with definition Ao = 3000, using DI water

Drying for 5 min.

6.4 Automatic Operation

Close door by means of door button until display shows following:

Program ready
Automatic Operation

In automatic mode, the machine is operated using automatic basket loading. Program selection and program start is initiated by automatic program recognition. As long as door is not closed, programs may be overwritten by means of program buttons.

6.5 User ID

Loading name No. by keypad or username by means of barcode reader for batch documentation.

With user ID active, as **door is op**en, the following indication is displayed:

User ID Name or Number?
--

The machine either reads a 2-digit number from the 6 program buttons from 11 – 66 or a text from barcode reader is entered. The respective number (e.g. 36) or the name is passed on to the printer or the digital recording system and assigned to the appropriate batch. A program may be started only following entry of this data, the SW remains with this interrogation and the program cannot be started until this data is received.

Input by means of keyboard:

If No. 66 is entered, text "No ID" is passed on.

If input is made without the use of a barcode reader, it is recommended to generate a list that assigns the number with the appropriate name.

Example

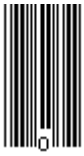
No.	**Name**
11	**Sr. A. Küttel**
12	**Sr. P. Wunderli**
66	**No ID**

Input by means of barcode reader:

Inputting No. 0 is passed on as "no ID".

Barcode Type: Code 39. Length of name is limited to 20 characters. Barcodes for simple programs may be generated by simple means. They are available free of charge via this internet address: http://www.barcodemagic.com/barcodemagic.html.

Barcode Type Code 39

	
Heike Martiny	**No ID / Exit**

The interrogation may be activated or deactivated in the configuration module 5.

6.6 Rack Recognition

Inputting rack No. by means of keypad or rack name by means of the barcode reader for batch documentation.

If **Rack Recognition** is activated, the following is displayed:

Rack Name or No.?
--

The machine either receives a 2-digit number from the 6 program buttons from 11 – 66 or it reads a text by means of the barcode scanner. The respective number (e.g. 36) or name is passed on to the printer or to the digital documentation system 8565 and is assigned to the respective batch. A program can be started only after the respective input has been received, the SW remains in interrogation mode until the data are received. In case of automatic rack loading, the machine cannot be started until after the input is completed.

Ionput by keyboard:

In case of input No. "66", text "No ID" will be passed on.

Input by barcode reader:

Upon inputting No. 0, resulting text is „no ID".

Barcode Type Code 39, length of name is limited to 12 characters.

The interrogation may be activated or deactivated in the configuration module 5.

6.7 Identification of batch content

Input No. Of wash good load (e.g. **sieve trays**) by keyboard or inputting name of wash goods load or number by barcode reader for batch documentation.

In case of active **Batch Content Identification**, **instead of „UC door open"**, the following display appears:

Input batch content
No = -- ?

The unit reads the double-digit number of the six program keys 11 – 66or a text or the No. with the barcode reader. The respective number (e.g. 36) or name, is passed on to the printer or the digital documentation system 8565 and is subsequently assigned to the respective batch.

The limit of items entered is 18. The input must always be complemented by the No. 0. It is impossible to enter the same name twice. A program can be launched only following this input, otherwise the SW keeps in place with the query. In case of automatic rack loading, program cannot be launched until after the input has been made.

Input by keyboard:

Input of No. 66 is passed on as "no ID" and the episode is terminated.

Input by barcode reader:

In case no item can be input, e.g. OP shoes, the procedure may be terminated by input No, 0. Text "no ID" is passed on.

Input procedure may be terminated at any time by the "IO" switch. All input data are erased.

Always finish the procedure by inputting No.0. On the display, the number of batches terminates the procedure.

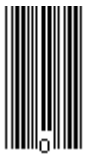
In case the maximum of 18 items is reached, instead of the indication "input batch content", display reads "max. batch No. reached". Input is terminated without inputting the usual No. 0 and the program may be launched.

No. of batches
12

The rack may be inserted.

Barcode Type Code 39 or EAN 13. The length of the name is limited to 12 characters or a 12-digit number.

Preferably, the barcode No. 0 is attached to the unit.



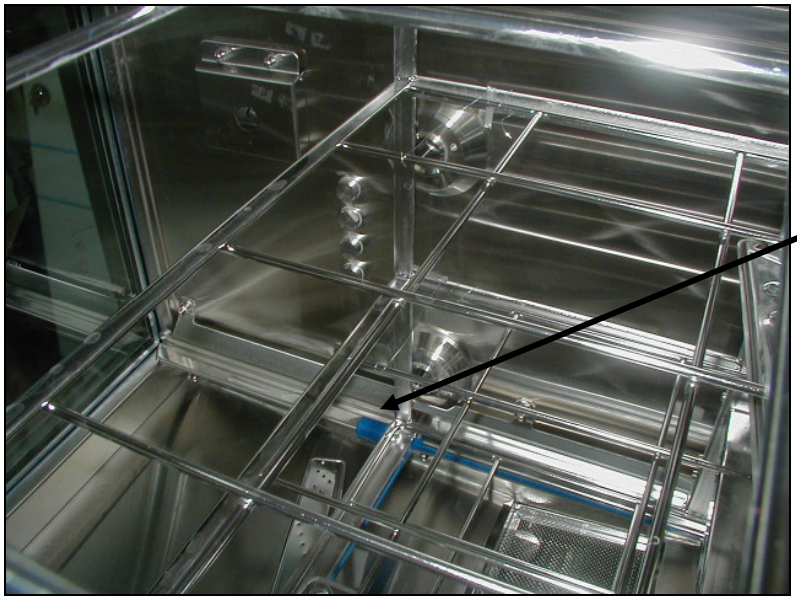
No ID / Exit

The interrogation may be activated or deactivated in the configuration module 5.

7. Program Start and Run

!IMPORTANT NOTES!

WD 230 and 250
The racks must always be inserted with the two blue plugs up front. Docking items on right hand side must match unit!



WD 290
In case of the WD 290, the racks is designed in symmetrical fashion, thus cannot be inserted the wrong way. Docking at bottom must be matching. The racks must not be pushed all the way to the rear wall, rather, it must be held cleanly in the center by the hold down clamps.

WD 290
Whit automated rack loading system rack must fit as shown blow in the picture

Rack must exactly fit opening.

At regular intervals education and In - service instruction of operators shall improve the cleaning quality.

Prevent lengthy contamination drying periods for medical products

Drive elements for drills and mills or complex medical products must be dismantled, subjected to ultrasonic cleaning or manual brushing prior to the automated decontamination process. Pay attention to instructions issued by the respective manufacturers.

Hollow bodies for drive elements of MIC instruments must generally be connected with the wash goods carrier by means of hoses, in order to enable disinfection of inner surfaces of the respective medical products.

Observe standard precautions, for example not touching mouth or eyes after handling contaminated goods or if handling items such as racks.

1. Check liquid detergent level. Refill if needed.
2. Open shut-off valves and engage power main switch.
3. Press 0-I button. Display will show „Program ready "
4. Press door button in order to open wash chamber, remove insert basket.
5. Load basket with wash goods. Make sure that water is always able to run off the wash goods and that all wash arms are unobstructed.
6. **Empty all containers**, remove all stops, tags, sealing wax remnants etc. The decontamination items must not be laid inside one another, thus covering up parts thereof
7. **Rotary spray arms must not be obstructed by items reaching to within their field of movement. Perform manual rotation test.**
8. Wash goods must not hang out over wash basket. As basket is inserted, the seal may be damaged by overhanging sharp objects.
9. **When inserting the basket into the wash chamber, water dockings to basket must meet docking hardware on machine!**
10. **!DANGER!**
    A fully loaded wash goods rack may weigh up to 100 KG. Caution, in case of dropping, operators risk injury.
11. With activated batch identification, the user, the rack and the rack content (sieve trays) may be input by means of the barcode reader.
12. Fully insert basket until basket clicks into raster of basket guide.
13. Close wash chamber door by means of door button (WD 250 and 290).
14. In case of the WD 230, it is imperative to listen to the distinctive 'click' of the handle when closing and the indication "program ready" must be displayed.
15. **!DANGER!**
    During the door closing process of the automatic sliding door (WD 250 and 290) ayn contact with the door and it immediate surroundings (adjacent cover components) must be avoided. Improper handling may cause injury to operator fingers.

16. The machine is now clear to start operation.
17. Press the desired program key. Watch for water intake. Display shows program name, followed by the respective program status.
18. While program is running, display continuously shows the current step in which the machine is operating, current temperature in the wash chamber and the remaining program running time.
19. The wash chamber door remains locked for the entire wash cycle.
20. In case of program interruption with the I/O button, the door of the unclean side will remain locked. Instead of the "program ready", the display shows "door locked". Only following the successful conclusion of the current program, in case of error and program abort, the door of the unclean side may be opened.
21. At program end, a beep sounds and the display shows „Program P3 properly completed". Open wash chamber on clean side by pressing of door button and remove the wash goods.
22. **!WARNING!**
Wash goods are hot! Risk of scalding . Racks and inserts must first be cooled down. Drain hot water remnants from all containers into the wash chamber. Immediately after opening of the wash chamber, do not touch heating elements, risk of scalding.
23. Close the clean side wash chamber door. If door button of unclean side is pushed while door of clean side is open, a warning beep will sound.
24. The door of the clean side can be opened only at end of program. Once the door of the unclean side is opened, the clean side can no longer be opened.
25. Display shows „Program ready ".

! IMPORTANT NOTE !

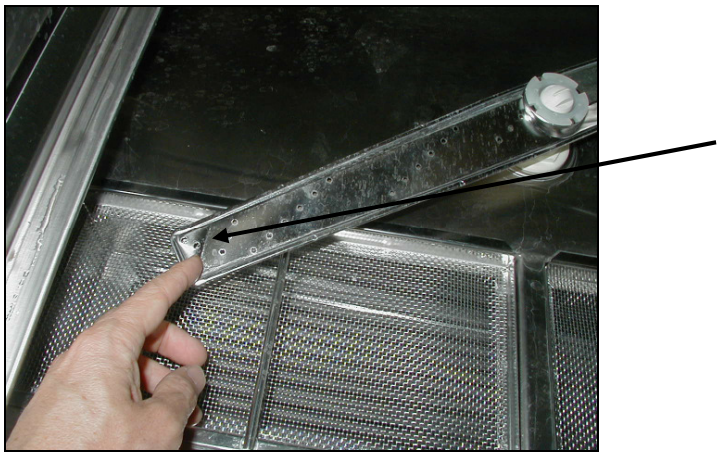
- WD 250 and 290: In powerless state, wash chamber door cannot be operated.
- Only **one** door can be opened at any one time.
- At no time a disinfecting program may be interrupted under any circumstances. At each interruption, the program must be restarted by means of the reset (ON - OFF) button.
- In case of errors with program interrupt or in case of a program stop by the user, the clean **and the unclean** side is not released. A program has to be finished till program correctly finished.
- In case of machine idleness for more than two days, an empty cycle is recommended for self-disinfecting.
- Machines with DI water preheating feature, stand-by mode is active only if machine is under power.

8. Wash Chamber Cleaning and daily Maintenance Chores

Only a machine that receives daily cleaning and preventive maintenance can operate properly.

! IMPORTANT NOTE !

- The wash chamber must be checked daily (especially at the end of the day) and clogged jets must be cleaned.



- The sieve system must be cleaned and potential foreign objects removed from the wash chamber.
- All sieves must be put exactly back where they belong.

The wash chamber must be checked daily. The sieve system must be cleaned and potential foreign objects removed from wash chamber.

The liquid level in the storage containers of applied additives must be checked daily, replenished if needed.

The customer (normally the technical service of the hospital) is responsible for periodic maintenance work according to instructions received. Completed maintenance work must be carried out according to checklist and documented on test protocol.

For maintenance work and support, consult our customer service.

!NOTES!

The machine housing may not be hosed down. The unit is not water jet protected.

!WARNING!

Take care during cleaning to prevent injury to hands or fingers. Camber may be hot . Sharp items and debris, such as sutures, wires, scalpel blades, or other items, may be present. Wear protective clothing and gloves and remove debris carefully.

9. At End of Usage

1. Close all water valves.
2. Turn off main power switch.

!WARNING!

Unless water valves are closed, machine should be shut down by means of the I/O switch only. Leave main switch in position "ON" in order to have the overflow safety of the wash chamber, i.e. the self protection of the machine remain in effect. In case of a defective intake valve, the wash chamber might otherwise be flooded.

10. Process safety / personnel protection / equipment protection

With an eye on standardizing th decontamination, disinfection and drying processes on top quality level, process safety in instrument reconditioning is an important prerequisite for the subsequent safe sterilization process. Therefore, all relevant process parameters must be monitored during the process. In case of deviations that our outside of pre-selected tolerances, the current process is interrupted and the respective deviation is shown on display.

Process safety

The following parameters are being monitored:

- If sufficient water is injected during filling step (monitoring of water level by means of level sensor P1).
- That no over- or under-dosing for cleaning and disinfecting additives are occurring (monitoring of pump performance by means of flow meters during dosing cycle, optional Q 1-4).
- That no undesirable dosing occurs during the process (flow rate monitoring by means of flow meters during process, optional Q 1-4)
- Sufficient remaining detergent level (empty indicator S201 – 205).
- If process temperature is under-reached or overshoots by 5°C from target value (NTC1).
- If temperature exceeds 45°C during cold pre-rinse (NTC1).
- If deviation between control sensor (NTC1) and monitoring sensor (NTC5) exceeds 2°C.

- If monitoring sensors are defective (resistance values outside of potential range, NTC 1-6).
- If pump or water pressure levels are insufficient during water steps (pump pressure switch S 211).
- If the liquid level is too low or too high during water steps (analog level sensor monitor P1).
- If water circulation is insufficient during water carrying steps (pressure differential switch for liquid level S 109).
- If there is no water leak during water carrying steps (leakage sensor, optional SD).
- If the automatic program recognition is defective (only for WD 290).
- If drain is stopped up following water steps. The subsequent water step may be launched only following complete drainage. The liquid level is being monitored during drain phase (P1).
- During drain cycle, pump pressure switch must be in open position (explanation: if a relay remains stuck, liquid continues to be re-circulated).
- If drying air supply is always sufficient (differential pressure monitoring across air filter, optional S212).

Clean door will be unlocked after completion of process only if all process parameters were found to be within predetermined range; display shows „Program properly completed ".

In case the current process is interrupted, program must be restarted from scratch.

Following improper process, both doors always remain locked

Personnel safety

The safety concept for personnel safety is designed as follows:

- With wash chamber door open, wash pump cannot be activated (risk of burns).
- The unclean door cannot be opened as long as machine is running or as long as there is wash liquid in the wash chamber.
- The unit can only be started with wash chamber doors closed.
- Once the door is closed, it is being monitored by means of the safety strip.
- The wash chamber glass door consists of double pane, hardened thermo safety glass.

Equipment protection in case of malfunction (mechanical and electrical)

- All electro heaters are equipped with a dry protection and an overheat protection for water and drying air that opens circuit on all phases (fire safety).
- The dryer heater can be activated only if there is a certain air pressure within the dryer heater (pressure switch P18).
- All motors for door drive, rack transport, pumps and blowers are equipped with thermal protection and overload protection (fire safety).
- The wash chamber is mechanically drained, (only while main switch is in ON position) if water level is higher than lower door edge (overflow protection S31).

10.1 Error Indication without Process Interrupt

Appears instead of „Program ready " and „Program 1 correctly terminated"

10.1.1 Dosing Agent Empty

Display

Dosing agent x
Empty

Cause:

The dosing agent in container x has been used up or the empty indicator float is defective or improperly set or wire terminals are without contact.

Remedy:

Refill dosing agent, check float switch, wiring on terminal at front side of electro enclosure.

A wash program can be started only after manual operation of 0 / I button.

Note:

Safe disinfecting and cleaning is assured only if all agents are available in sufficient quantities.

When handling cleaning and disinfecting agents: protect eyes, hands and clothing. For handling agents, wear gloves, do not ingest., avoid contact with skin and eyes.

Wash immediately in fresh water if you come into contact with any solution

10.1.2 No Program Recognition

Display

Program recognition
Error code 118

Cause:

With automatic program recognition active (ON or ONLY), Reed sensors are tested for their function. Is one of the sensors defective, error Program recognition is displayed.

Remedy:

Take rack out of the washer and put it back.

Check if all Sensors S 101, 102, 103, 106, 107 or 108 closes with a magnet.

Set Basket Coding to Off (Configuration).

10.1.3 Door Interlock Unclean Side

Display

Door Interlock
Restart a program

Cause:

If a program got interrupted with the I/O button, during a program cycle, the UC door stays interlocked . On the display instead of "Program ready" "Door Interlock" is shown.

This is a precautionary measure for the user in case of a malfunction of the washer.

In case of active suppression of liquid drain BGA „Drain at interrupt OFF" or at BGA program.

Door of unclean side remains locked (even after supply cut-off by main switch), if there remains any water in the wash chamber (P1 not below empty level). It may be opened only once the remaining water has been drained. Instead of ready mode, display shows „Door interlock".

Remedy:

The Door can be opened only if a program is run successfully till to the end or by cut off the main switch.

The remnant water in the chamber must be drained.

10.1.4 Sensor Differential

Display

Sensor differential is excessive

Cause:

The difference between monitoring NTC 1 and control sensor NTC 5 is excessive (greater than ± 2°C). This query only is active during the water steps. A new program **may** be activated.

Remedy:

Temperature sensors NTC 1 and NTC 5 has to calibrate at at least 80 °C by means of a reference sensor. The defective sensor must be replaced. Notify technical service.

10.1.5 Sterile Filter must be replaced

Display

Replace Filter

Cause:

The sterile filter for the dryer system is clogged, must be replaced respectively. The filter monitor with differential pressure switch at the dryer blower (S212) has closed. A new program **may** be activated again.

Remedy:

Exchange filter. Notify technical service.

10.1.6 Maintenance Indication, Maintenance Intervals

!Periodic Service!

Cause:

Maintenance warning after a predetermined number of batches processed (normally every 1000). The maintenance frequency may vary according to application, environmental conditions, water quality etc. A new program **may** again be activated.

Remedy:

Service through contract partners. Increase batch quantity by 1000.

10.1.7 Failure of House side Exhaust System

Display

Exhaust system defective

Cause:

The building side exhaust system has failed, external, potential-free contact has closed (S213). A new program **may** be activated.

Remedy:

Call technical service.

10.1.8 Load Cut-Off (external)

Display

Peak-load cut-off

Cause:

The peak-load management has cut off the automat (input SA closed). A new program **cannot** be activated until the user is released for service.

10.1.9 No communication with ICS 85XX (external batch documentation system)

Reference on display

No communication with batch doc. system

Cause:

If PC for batch documentation system using the ICS 85X5 is not running any more, ceases operation or connection with the RS 485 interface is interrupted, error „No communication " is displayed. A new program may be started again.

Software:

If in Config 2 the address for the RS 485 is not = 0, the interface RS 485 is checked for communication during standby operation. If communication is lost for 10 seconds, instead of "Program", an error is displayed.

Remedy:

Restart PC or check the connection to the PC.

10.1.10 The Machine does not clean properly

1. Are all water valves open ?
2. Is there sufficient cleaning and disinfecting agent available in containers ?
3. Are dosing lines clean and open ?
4. Are suction or intermediate sieves clogged ?
5. Are jets on wash arms clogged ?
6. Are basket dockings operating properly ?
7. Are wash jets on basket clogged ?
8. Is basket properly inserted ?

9. Has the appropriate program been selected ?

10.2 Error Indication with Process Interrupt

Instead of program indication, an error is displayed.

Except for error code 101, display 1 and 2 alternate blinking with error cause.

Display 1	**Explanation**
Door is open	Short text error cause
Error code 100	Error code No (see error code overview in Tech. Manual)
Display 2	**Explanation**
Tech. Service 145	Individual error indication in configuration module
Progr. 3 Step 3.1	Interrupt in program 3, step 3, phase I of II

11. Machine does not operate

1. Has main power switch been engaged ?
2. Are all fuses intact ?
3. Has machine door been properly closed ?
4. Watch error code on display !

Should you need the assistance of your service center, be prepared to give exact information as to which operations have been done and which error codes have been indicated. If a printer is connected, print out the operational conditions at time of machine failure. Have the serial number of the affected machine available for the service center. This number is found on the machine tag.

12. Activate Modem Connection

If a modem is installed in machine, unit may be connected with the Belimed service center. Prior to connecting, the service center must be alerted by phone.

Display	**Explanation**
Program ready 27.04.2001 11:36	In stand-by mode, press **IO** button for 4 seconds.
Password ? ---	If display shows "Password", press Door button for 4 seconds.
Remote Support Initialize Modem	The modem connection is being established.
Remote Support Not Connected	The modem connection could not be established.
Remote Control Connected	The modem connection is established. The machine is under remote control.

13. Conformity

We declare under our own responsibility that according to annex IX of directive 93/42EEC we meet all provisions of the directive 93/42/EEC which apply.

Applied harmonized standards, national standards or other normative documents:

- EN 1441
- EN 61326-1
- EN 61000-3-2, EN 61000-3-3
- EN 61010-1, EN 61010-2-040
- SVGW W/TPW 106 (05/2000), EN 61770, DVGW
- DIN EN ISO 9001:2000 / EN 13485
- (preISO EN 15883-1;2004 6)

Notified Body:

RWTüV Zert.Nr.: 04105553

13. Manufacturer, Maintenance and Service

The maintenance and the service activities are provided by the Belimed AG Customer Service Organization.

For support in Switzerland contact:

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